2012 Medicare Part D Medication Therapy Management (MTM) Programs

November 12, 2012

FACT SHEET

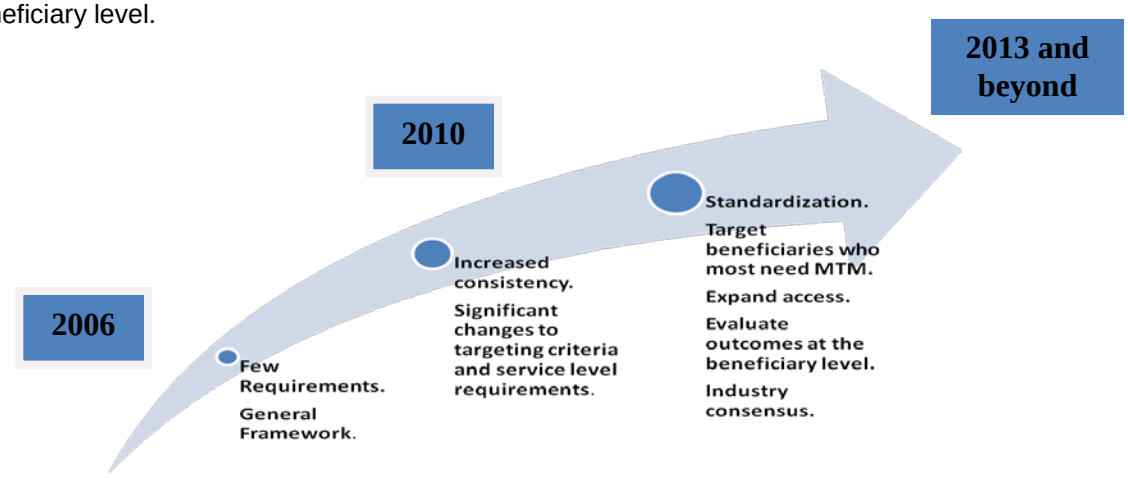
Medicare Part D Medication Therapy Management (MTM) programs have included expanded program requirements since 2010, and additional MTM improvements have been implemented to further strengthen these programs through provisions of the Affordable Care Act (ACA). This Fact Sheet presents a summary of the MTM programs in place for 2012 and discusses future enhancements.

BACKGROUND

The Medicare Modernization Act of 2003 (MMA) under title 42 CFR Part 423, Subpart D, established the requirements that Part D sponsors must meet with regard to cost control and quality improvement including requirements for MTM programs. The initial CMS regulations for these programs for 2006 established few requirements and a general framework that allowed sponsors flexibility to promote best practices. Industry practice influenced CMS' direction.

After an extensive analysis, the requirements were expanded in 2010 for increased consistency among the programs, and CMS pushed the industry forward. Significant changes were made to the targeting criteria and CMS required a minimum level of MTM services that must be offered to the Part D beneficiaries who qualify for these programs.

For the coming years, we expect increased standardization and industry consensus. CMS would like to expand access to better target the beneficiaries who most need MTM. In addition, through expanded data collection, we want to be better positioned to evaluate the impact of MTM at the beneficiary level.



REVIEW OF 2012 MEDICATION THERAPY MANAGEMENT PROGRAMS

Part D MTM program requirements are described in Chapter 7 of the Prescription Drug Benefit Manual[1] and are summarized within this Fact Sheet when applicable. Each Part D sponsor is required to incorporate an MTM program into their plan's benefit structure. These requirements do not apply to Private Fee for Service (PFFS) organizations, as described in 42 CFR §422.4 (a)(3). However, considering PFFS organizations have an equal responsibility to provide a

[1] Prescription Drug Benefit Manual. Chapter 7-Medication Therapy Management and Quality Improvement Program. Accessed June 30, 2012. http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/MTM.html

quality Part D product, CMS encourages these organizations to establish an MTM program for Medicare beneficiaries. Annually each spring, sponsors submit an MTM program description for CMS to review and approve for the next contract year.[2] Additionally, to promote evolving MTM best practices and to consider the best interests of the Medicare beneficiary, CMS allows certain mid-year positive changes to the Part D sponsors' approved MTM program. Part D sponsors may request changes for approval during specified update windows.[3]

In 2012, there are 633 active Part D contracts with an approved MTM program including 550 Medicare Advantage prescription drug plans (MA-PDs) and 83 standalone prescription drug plans (PDPs). This compares to 641 contracts (557 MA-PDs and 84 PDPs) in 2011. All sponsors who are required to establish an MTM program in 2012 have an approved program in place. Throughout this Fact Sheet, these are referred to as MTM programs. Employer contract MTM programs are included in the statistics for PDPs. This analysis includes characteristics of 2012 MTM program applications approved during the spring annual review and changes approved during the September 2011 and March 2012 update windows as of May 1, 2012.

Eligibility Criteria

Part D enrollees who have multiple chronic diseases, are taking multiple Part D drugs, and are likely to incur annual costs for covered Part D drugs that exceed a predetermined level are targeted for the MTM programs, as described in § 423.153(d)(1). The cost threshold is based on total gross Part D drug costs (including both plan and beneficiary costs) and was lowered to $3,000 in 2010 and 2011. In 2012 and subsequent years, this cost threshold will be increased by the annual percentage specified in §423.104(d)(5)(iv). The 2012 MTM program annual cost threshold is $3,100.20.

Criteria 1: Have Multiple Chronic Diseases

Sponsors are required to target beneficiaries with multiple chronic diseases, and they define the minimum threshold for eligibility into their MTM program. In 2010, CMS established both a ceiling and a floor for the minimum number of chronic diseases that may be required. Therefore, a plan sponsor has the discretion to determine whether to target beneficiaries with at least two chronic diseases or at least three chronic diseases. Figure 1 shows the percent of MTM programs by the minimum number of multiple chronic diseases that they target. Approximately 79% of the current programs target beneficiaries with a minimum of three chronic diseases, which is consistent with 2011.

[2] Memo: Contract Year 2012 Medication Therapy Management Program (MTMP) Submission. Accessed June 30, 2012. http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/MTM.html

[3] Memo: Process for Part D Sponsors to Request Changes to a Medication Therapy Management Program (v03.12.12) Accessed June 30, 2012. http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/MTM.html

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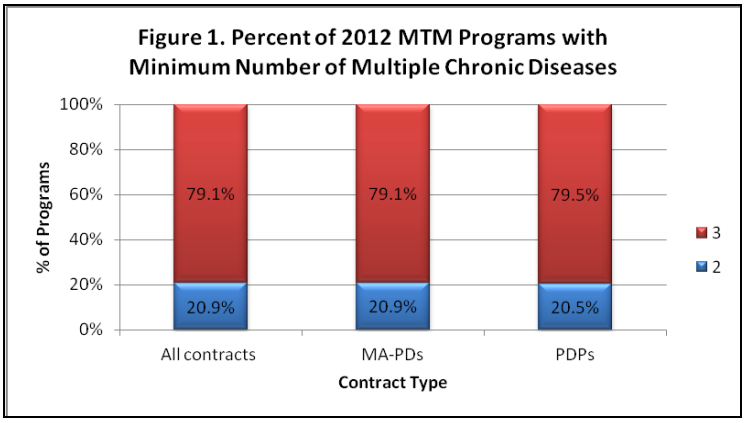

Sponsors may target beneficiaries with any chronic diseases or limit enrollment in their MTM program to beneficiaries having specific chronic diseases. Sponsors are encouraged to consider including diseases in their targeting criteria to meet the needs of their patient populations and improve therapeutic outcomes. In defining multiple chronic diseases for eligibility, 2.7% of 2012 programs are targeting beneficiaries with any chronic diseases, and 97.3% are targeting beneficiaries with specific chronic diseases. More programs in 2012 are targeting beneficiaries with specific diseases than in 2011 (6.1% of programs targeted beneficiaries with any chronic diseases and 93.9% targeted beneficiaries with specific chronic diseases in 2011).

At a minimum, sponsors must include at least four of the following seven core[4] chronic diseases: Hypertension, Heart Failure, Diabetes, Dyslipidemia, Respiratory Disease (such as Asthma, Chronic Obstructive Pulmonary Disease (COPD), or Chronic Lung Disorders), Bone Disease-Arthritis (such as Osteoporosis, Osteoarthritis, or Rheumatoid Arthritis), and Mental Health Diseases (such as Depression, Schizophrenia, Bipolar Disorder, or Chronic and disabling disorders). CMS expanded these requirements for next year. In 2013, if sponsors choose to target beneficiaries with specific chronic diseases, they must include at least five of nine core chronic conditions, and Alzheimer's Disease and End-Stage Renal Disease will be included as core chronic diseases.

The most frequently targeted diseases in 2012 are closely aligned with the same top diseases included as part of the targeting criteria for MTM programs since 2007. Figure 2 provides the percentage of MTM programs for 2012 that target beneficiaries with these top ten diseases. Diabetes, Heart Failure, Hypertension and Dyslipidemia are the top targeted diseases. Overall, the top ten targeted diseases align with the top drugs and classes of drugs utilized by Medicare Part D beneficiaries, which are Cardiovascular, Psychotherapeutic agents, and Antihyperglycemics.[5]

Other beneficiary conditions that are targeted by more than 10% of these programs include: Bipolar Disorder (18.8%), Alzheimer's Disease (15.5%), Osteoarthritis (12.3%), HIV/AIDs (10.3%) and Stroke (10.0%). When submitting MTM program applications, sponsors are allowed to make multiple selections to denote all of the specific chronic diseases that they are targeting.[6]

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[4] Based on an analysis performed prior to release of the 2010 Call Letter, these conditions are prevalent in the Medicare population based on the analysis of the RxHCC Risk Adjustment model, pose a risk to the Medicare Trust Fund, and were already the most common diseases targeted by Part D MTM programs.

[5] CMS 2012 Medicare Prescription Drug Benefit Symposium. State of Part D: 2006-2012. Cynthia G. Tudor, PhD. March 20, 2012. Presentation accessed June 30, 2012 at: http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/ProgramReports.html

[6] These are not mutually exclusive.

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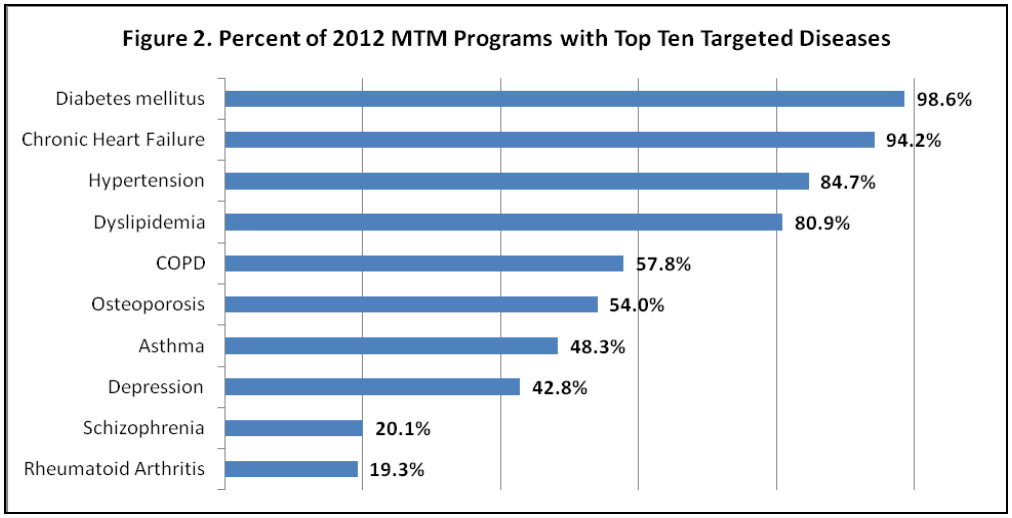
Sponsors should target beneficiaries with any combination of the chronic diseases included in their criteria.



Criteria 2: Taking Multiple Covered Part D Drugs

Each program sets the minimum number of covered Part D drugs a beneficiary must have filled for MTM program eligibility. The MTM requirements establish both a ceiling and a floor for the minimum number of drugs that may be required, and sponsors may set this minimum threshold at any number equal to or between two and eight. For example, one sponsor may specify that a beneficiary must have filled a minimum of five covered Part D drugs to be targeted for their MTM program (along with meeting the other two MTM targeting criteria), whereas another sponsor may specify that the beneficiary must have filled a minimum of two covered Part D drugs.

The percent of 2012 MTM programs that target beneficiaries with the respective minimum number of covered Part D drugs is provided in Table 1 in aggregate and broken out by MA-PDs and PDPs. Approximately 61.5% of programs target beneficiaries who have filled at least eight covered Part D drugs, compared with 60.5% in 2011. A recent analysis of 2010 Prescription Drug Event (PDE) data found that, on average, Part D enrollees have 3.3 prescriptions fills per month, and 37.1 fills per year, compared to MTM-eligible Part D enrollees who on average have 83.2 annual fills.[7]

Table 1. Percent of 2012 MTM Programs with Minimum Number of Covered Part D Drugs

Minimum Number of Covered Part D Drugs	% of all MTM Programs	% of MA-PD MTM Programs	% of PDP MTM Programs
2	6.3%	6.4%	6.0%
3	0.8%	0.9%	0.0%
4	2.1%	1.8%	3.6%
5	7.6%	7.8%	6.0%
6	8.7%	7.8%	14.5%
7	13.1%	13.1%	13.3%
8	61.5%	62.2%	56.6%

[7] CMS 2012 Medicare Prescription Drug Benefit Symposium. State of Part D: 2006-2012. Cynthia G. Tudor, PhD. March 20, 2012. Presentation accessed June 30, 2012 at: http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/ProgramReports.html

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Sponsors indicate in their MTM program application if any covered Part D drug applies, if chronic/ maintenance drugs apply, if disease-specific drugs related to the chronic diseases apply, or if specific Part D drug classes apply. Over one-third (39.7%) of programs allow any Part D drug to qualify for this requirement, similar to 2011 (37.9%). The remaining programs require Part D drugs for chronic conditions (42.8%), disease-specific drugs related to chronic diseases (4.9%), or specific Part D drug classes (12.7%).

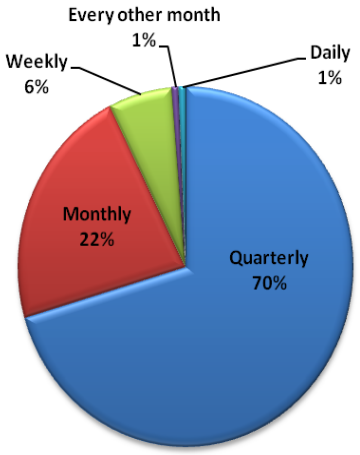
Criteria 3: Likely to Incur $3,100.20 for Covered Part D drugs

The sponsor must provide a description of the analytical procedure used when determining if a beneficiary is likely to incur this annual cost threshold for 2012. The description may include the specific threshold(s), formula, or criteria on their model used. MTM programs in 2012 continue to apply varying costing methodologies, but the majority of analyses are based on annual projections for Part D covered drug costs in the previous quarter or the previous month. A number of programs also use historical data from the past 12 months.

Method of Enrollment

Sponsors must enroll targeted beneficiaries using an opt-out method of enrollment only and must target beneficiaries for enrollment in the MTM program at least quarterly during each plan year. Almost three-quarters (70.5%) of the programs identify targeted beneficiaries quarterly and almost one-quarter identify beneficiaries monthly (Figure 3). This is comparable to results reported in previous MTM Fact Sheets.

Figure 3. Frequency of Identification: Percent of 2012 MTM Programs



All of the MTM programs use drug claims data to identify eligible beneficiaries for their MTM programs in 2012. In addition, 29.1% of MTM programs use medical claims data to identify eligible beneficiaries. Similar to 2011, it is more likely in 2012 for MA-PD programs to use medical claims data to identify eligible beneficiaries (31.5% of MA-PD programs versus 13.3% of PDP programs). Sponsors use other types of data to aid with identification, and 2.2% use information collected from the beneficiaries, and 1.9% use lab data. These are not mutually exclusive categories.

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MTM Program Services

Sponsors must provide a minimum level of MTM services for each beneficiary enrolled in the program that includes interventions for beneficiaries and prescribers, offering an interactive comprehensive medication review (CMR) by a pharmacist or other qualified provider at least annually with written summaries, and performing quarterly medication reviews with follow-up interventions when necessary. Sponsors may offer additional value-added services beyond the required services.

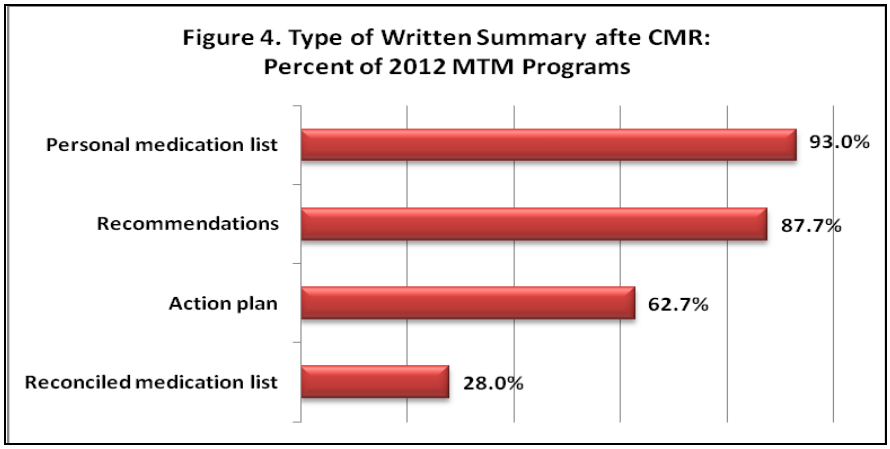
Beneficiary Interventions

Since 2010, 100% of MTM programs offer CMRs at least annually, unless the beneficiary is in a long-term care (LTC) setting, and perform targeted medication reviews at least quarterly. These are required interventions. Beginning in 2013, per the ACA, sponsors must offer a CMR to all MTM enrollees at least annually, including LTC beneficiaries.

A CMR is a review of a beneficiary's medications, including prescription, over-the-counter (OTC) medications, herbal therapies, and dietary supplements, that is intended to aid in assessing medication therapy and optimizing patient outcomes. The CMR must be completed through an interactive person-to-person consultation with the eligible beneficiary. This real-time interaction may be face-to-face or through other interactive methods such as the telephone or through telehealth technologies. Every program offers the interactive, person-to-person CMR consultation via the phone, and over one-fourth (28.4%) of programs also offer face-to-face consultations (up slightly from 25.8% in 2010 and 27.0% in 2011). Currently, less than 1% of programs offer CMRs through telehealth technologies.

Furthermore, sponsors must implement a systematic process to summarize the interactive consultation. Sponsors must provide an individualized written summary to the beneficiary (e.g. a personal medication list, reconciled medication list, action plan, or recommendations for monitoring, education, or self-management). A personal medication list is a list of medications currently in use by the beneficiary, and a reconciled medication list involves a formal medication reconciliation process to create a complete list of medications with comparison to the patient records or medication orders.

Figure 4 ranks these top four types of written summaries that are provided to beneficiaries pursuant to a CMR in 2012. Multiple selections were allowed.



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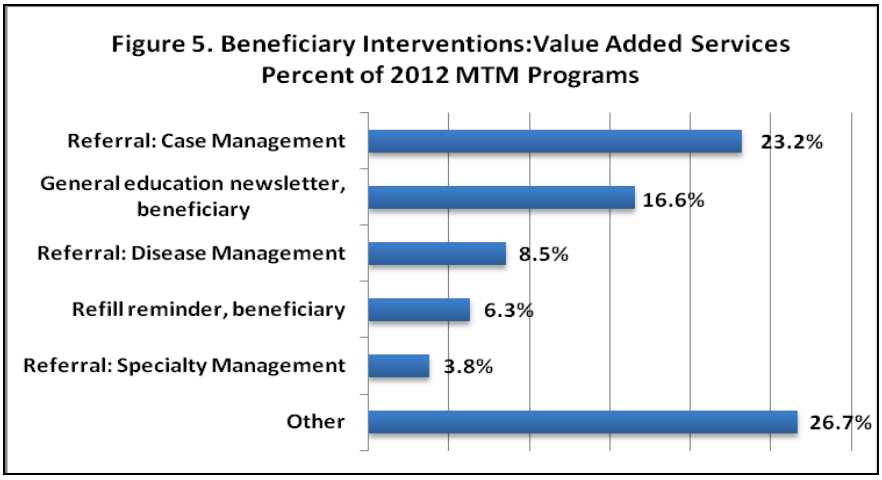
The ACA further required that the Secretary, in consultation with relevant stakeholders, develop a standardized format for the CMR action plan and summary. Development of the standardized format is complete and involved significant consultation with stakeholders and included an environmental scan, literature review, public comments, expert panel review, and testing with beneficiaries, providers, and Part D sponsors. The format includes three components: Beneficiary Cover Letter, Medication Action Plan, and Personal Medication List.[8] The purpose of the Beneficiary Cover Letter is to remind the beneficiary of the CMR, introduce the Medication Action Plan and Personal Medication List and describe how the beneficiary can contact the MTM program. The Medication Action Plan helps the beneficiary with resolving issues of current drug therapy and to achieve the goals of medication treatment. The Personal Medication List is a list of all the medications in use (i.e., active medications) by the beneficiary at the time of a CMR. Part D sponsors must begin using the standardized format in January 2013.

Sponsors are not required to offer the CMR in 2012 to targeted beneficiaries enrolled in the MTM program who are in a long term care (LTC) setting. Sponsors must still perform quarterly medication reviews and offer interventions targeted to the beneficiaries' prescribers, as these are requirements for all beneficiaries enrolled in the program regardless of setting and regardless of whether or not they decline the CMR offer. The targeted medication reviews assess medication use and monitor whether any unresolved issues need attention, new drug therapy problems have arisen, or if the beneficiary has experienced a transition in care. Part D sponsors provide follow-up interventions as necessary.

Beyond the required services, sponsors provide additional value added services as shown in Figure 5. In 2012, referral for case management will be provided by 23.2% of programs and general education newsletters by 16.6%. The 'Other' beneficiary interventions represent a variety of over 40 different miscellaneous interventions to improve medication use or perform utilization management. Multiple selections were allowed.



Prescriber Interventions

Sponsors are required to offer interventions to the beneficiaries' prescribers. Therefore, 100% of MTM programs offer interventions to prescribers to resolve drug therapy problems or optimize therapy. Over 20% (20.7%) also provide a patient medication list to the prescriber. In their 2012

[8] The standardized format with detailed instructions for implementation, and frequently asked questions are posted on the CMS MTM web page at: http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/MTM.html

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MTM program application, sponsors indicate the methods of delivering these interventions to the prescriber: 84.0% fax the consultations (down from 92.0% in 2011), 77.7% provide phone consultations (77.5% in 2011), and 69.0% provide mailed consultations (78.9% in 2011). Sponsors may use multiple methods of communication.

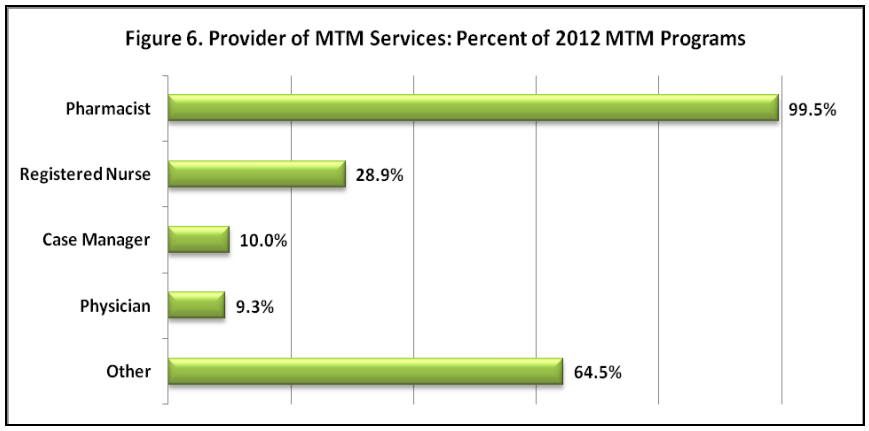
MTM Providers

MTM is considered an administrative cost (that is, a component of the plan's bid) by CMS. Part D Sponsors are required to explain how their fees account for the time and resources associated with their MTM program. They have the flexibility to determine the billing mechanisms and establish fees for pharmacists and other qualified providers associated with providing the MTM services. These arrangements are between the Part D sponsors and the providers of the services. Per the requirements for professional health claims, if MTM providers bill Part D sponsors electronically for MTM services, such billing claims can be transmitted using the ASC X12 837 P Version 4010/4010A1 or NCPDP 5.1 standards. Both X12 837 and NCPDP 5.1 support CPT codes and HCPCS codes. Proprietary codes are not permitted under HIPAA.

Sponsors can utilize internal staff, outside personnel or both for delivery of MTM services (multiple selections are allowed). In 2012, 34.9% of programs utilize internal staff (down from 46.8% in 2010 and 37.0% in 2012), and 84.2% of programs utilize outside personnel (up slightly from 81.6% in 2011 and 80.0% in 2010). These trends are similar for MA-PDs and PDPs. In previous years, a higher share of MA-PDs used outside personal compared to PDPs (alone or in combination with internal staff).

Per CMS' requirements, the MTM services may be furnished by pharmacists or other qualified providers. Sponsors indicate if their MTM providers are pharmacists, physicians, registered nurses, and/or others. These are not mutually exclusive, and sponsors may utilize any single type of qualified provider or any combination of providers. In addition, plan-reported data do not distinguish between providers of the CMR and providers of other services at this time.

Compared to previous program years, pharmacists continue to be the leading provider of MTM services (Figure 6). Overall, regardless of whether the sponsor is utilizing in-house and/or outside personnel, in 2012 almost all of MTM programs (99.5%) utilize pharmacists to provide the services. About 9% (9.3%) of programs utilize physicians and almost 29% (28.9%) utilize registered nurses. A large proportion of programs utilize other support staff to assist in providing these services (64.5%), including pharmacy technicians, patient care coordinators/case workers, pharmacy students, and MTM assistants.



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As mentioned above, almost 85% of programs utilize outside personnel. Outside personnel may include a Prescription Benefit Management (PBM) company, MTM vendor, disease management vendor, community pharmacists, LTC pharmacists, or others. Of the programs that utilize outside personnel, 58.7% utilize a PBM (49.4% of all 2012 MTM programs), 12.9% utilize a disease management vendor (10.9% of all programs), 52.2% utilize an MTM vendor (43.9% of all programs), 27.0% utilize community pharmacists (22.7% of all programs), 13.3% utilize LTC pharmacists (11.2% of all programs), and 2.4% utilize other outside personnel (2.1% of all programs).

Compared to 2011, higher shares of programs are utilizing disease management and/or MTM vendors for 2012. The percent of programs using community pharmacists to provide MTM services also increased slightly compared to 2011. However, it is possible that the share of programs that utilize community pharmacists is under reported because a number of MTM vendors utilize a network of community pharmacists to provide these services, but the sponsor may only indicate that they use an MTM vendor as part of their MTM program submission.

SUMMARY

Medicare's requirements for MTM programs were significantly enhanced in 2010, and sponsors continue to implement robust MTM programs in 2012. The targeting criteria implemented by sponsors per CMS requirements have been generally stable. Almost 80% continue to target beneficiaries with 3 or more chronic diseases. Most sponsors target beneficiaries with specific conditions, and these align with the most prevalent chronic conditions in Medicare. Over 60% of the programs require beneficiaries to be taking 8 or more Part D drugs. The annual cost threshold was increased to $3,100.20 for 2012.

Over 70% of programs determine the eligibility of beneficiaries quarterly and 22% do so monthly, similar to 2011. All MTM programs in 2012 offer beneficiaries a CMR consultation over the phone. The percent of programs who also offer face-to-face CMRs has been increasing since 2010. Over 28% of programs offer a face-to-face CMR in 2012. Substantially all programs utilize pharmacists to deliver MTM services, and a higher share of programs are using outside personnel versus in-house staff, including disease management vendors, MTM vendors, and community pharmacists.

Section 10328 of the ACA specified changes to Part D MTM programs to further strengthen the MTM programs offered to Part D beneficiaries. Several changes were already implemented in 2010. Sponsors will be required to offer a CMR to all enrolled beneficiaries, eliminating the exception for beneficiaries in long-term care settings as of January 2013. The ACA directed the Secretary, in consultation with relevant stakeholders, to develop a standardized format for the CMR action plan and summary, effective January 2013. The provision of the written summary in the standardized format requires certain minimum service levels for the CMR, which include discussion of the beneficiary's concerns with their drug therapy, collection of the purpose and instructions for using their medications, review of a beneficiary's medications including prescription, non-prescription drugs and supplements to aid in assessing medication therapy, and engaging beneficiaries in management of their drug therapy.

CMS is focused on identifying potential opportunities to increase awareness of MTM programs among beneficiaries and their healthcare providers. Expanded information about MTM is available for beneficiaries in the *Medicare and You Handbook*, and there will be easier access to plan-specific MTM information within Medicare Plan Finder for 2013 open enrollment. CMS encourages sponsors to engage in outreach efforts to promote beneficiary participation in MTM programs, and beginning in 2013, sponsors are required to include information about MTM programs on Part D plan websites. Additional information has also been shared with the State Health Insurance Assistance Program (SHIP), a national program that offers one-on-one

counseling and assistance to people with Medicare and their families. CMS is reaching out to prescribers and other healthcare providers as well, to make them aware of changes to Part D MTM programs as of January 2013. We are including some basic MTM information in the upcoming Dear Doctor Announcement Letter. We also distributed a Medicare Learning Network article about MTM.

In the 2013 Call Letter, we proposed an MTM measure for the 2013 Part D Display Measures and then proposed a transition of that measure to the 2014 Part D Plan Ratings, based on the Pharmacy Quality Alliance (PQA) approved measure, "Completion Rate for Comprehensive Medication Review (CMR)". This measures the percentage of MTM-eligible beneficiaries who received a CMR (annual interactive person-to-person or telehealth consultation with written summaries as described in this Fact Sheet). The use of this MTM measure in Part D serves to promote the delivery of CMRs and should increase the number of beneficiaries who receive CMRs. CMS will consider other MTM quality or outcomes measures when developed and endorsed through a public consensus process.

CMS began a two year study in August 2011 to evaluate the impact of MTM on high risk, chronically ill populations. This study is analyzing the impact of CMRs and MTM services on improving safety and lowering costs. The results will be presented to stakeholders when available.

QUESTIONS

Questions regarding this Fact Sheet may be sent to: partd_mtm@cms.hhs.gov.